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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,572

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David Burton

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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,572	Applicant(s) BURTON, DAVID	
	Examiner Annette F. Dixon	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11,14-26,29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-11, 14-26, 29, and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed on March 4, 2009. Examiner acknowledges claims 1, 2, 4-11, 14-26, 29, and 30 are pending in this application, with claims 1, 8, 14, 15, and 17 having been currently amended, and claims 3, 12, 13, 27, 28, 31 and 32 having been cancelled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4, 6-11, and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton (WO 97/16216) in view of Sullivan (5,243,971) and John et al. (6,385,486).

As to Claim 1, Burton discloses an air delivery interface (mask 19) associated with an air delivery device (20) (Page 12, Lines 9-11) and a patient interface means (10) including one or more electrodes to monitor EEG (Page 10, Lines 25-30), where a control system (14) is utilized to monitor sleep stages (Page 11, Lines 9-12). Yet Burton does not expressly disclose the structure of the mask nor the placement of the EEG sensors upon the mask. However, at the time the invention was made the structure of the mask and the placement of the EEG sensors on the mask were known. Regarding

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the structure of the mask, Sullivan discloses a mask assembly (11, Figure 8a) comprising: a body (the combination of elements 24, 34, and 13) having an inner surface (34), and external surface (24) and a perimeter surface (13); and a forehead support (31) connected to the body (the combination of elements 24, 34, and 13). Further, Sullivan discloses a bar (30) extending in a lateral direction from the forehead support (31). Sullivan discloses a support pad (31) in contact with the forehead of the patient. Where these features of the mask are utilized to secure and fit the mask to the forehead of the patient. (Column 4, Lines 45-55). Regarding the placement of the EEG sensors, John teaches EEG electrodes are placed in pairs about the body in numerous places including the FP1/FP2 for the purpose of evaluating the state of the brain. (Column 10, Lines 27-32). Therefore, it would have been obvious to one having ordinary skill in the art to modify the device of Burton to include the structural forehead support and support bar as taught by Sullivan to enable the attachment of the mask to the patient's forehead, and to include the placement of the EEG sensors in the FP1 and FP2 Locations as taught by John for the purpose of detecting the state of the brain.

As to Claim 2, Sullivan teaches the perimeter surface (13) includes a padding material having a thermosensitive coating. Specifically, Sullivan discloses the membrane is molded from a soft, flexible plastic material. Intrinsically, as the perimeter surface (13) is made from a softer and different material than the rest of the mask (11) the perimeter surface (13) is more sensitive to temperature.

As to Claims 4 and 11, Burton discloses additional sensors such as blood oxygen saturation may be utilized to calculate the physiological data of the patient. (Page 6,

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Lines 14-23). Regarding the location of the sensor on the forehead, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change the location of the blood oxygen sensor to the forehead support, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As to Claims 6, Sullivan teaches a strap (the combination of elements 42 and 43) extending from the mask (11), and wherein a physiological sensor is located on the strap. Regarding the location of the sensor on the strap, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change the location of the sensor to the strap, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As to Claim 7, Burton discloses the use of sensors (30) to measure EOG. (Page 6, Lines 14-23)

As to Claims 8, 14, 17, 18, and 20, please see the rejection of claim 1. Regarding the plurality of sensors, Burton discloses a plurality of sensors utilized to calculate EEG, EOG and EMG (Page 6, Lines 14-23).

As to Claim 9, Burton discloses an EMG sensor (Page 6, Lines 14-23).

As to Claim 10, Burton teaches the use of physiological sensors such as ECG (Page 3, Line 20 and Page 4, Line 15).

As to Claims 15 and 19, Burton discloses the use of pulse oximetry sensor and an ECG sensor (Page 3, Line 20, Page 4, Line 15, and Page 6, Lines 14-23) yet does not expressly disclose the location of the sensors.

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As to Claim 16, Burton discloses an EMG sensor (Page 6, Lines 14-23 and Sullivan discloses the use of a strap (the combination of elements 42 and 43); yet the placement of the sensors on the strap has not been discussed. Regarding the location of the sensor on the strap, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change the location of the sensor to the strap, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

4. Claims 23-26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton (WO 97/16216) in view of Sullivan (5,243,971) and John et al. (6,385,486), as applied to claim 14, 17, and 18 above, and further in view of Miles (5,353,788).

As to Claims 23 and 26, the system of Burton/Sullivan/John discloses a mask assembly, yet does not expressly disclose the use of temperature sensors nor the location of the temperature sensors on the mask. However, at the time the invention was made the use of temperature sensors and their location was known. Specifically, Miles discloses a first thermal sensor (Column 4, Lines 55-60) on the interior surface (Column 4, Lines 33-37) and a second thermal sensor (Column 4, Lines 33-37). Miles discloses detecting a temperature change (via processor, 12) in the first or second thermal sensor (Column 5, Lines 20-68 and Column 6, Lines 1-30), where the temperature sensors are utilized to detect the nasal/oral airflow and to detect the temperatures of the body in order to monitor the physiological data of the patient to optimize settings. (Column 7, Lines 64-67). Regarding the location of the sensor near

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the mouth, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change the location of the sensor near the mouth, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Burton/Sullivan/John to include the temperature sensors on the mask as taught by Miles for the purpose of optimizing and monitoring the physiological data of the patient.

As to Claims 24, 25, and 29, the system of Burton/Sullivan/John discloses a mask assembly, yet does not expressly disclose the use a body movement monitor. However, at the time the invention was made the use of a body movement monitor sensors and their location was known. Specifically Miles disclose the detection of body movement via a sensor (Column 7, Lines 45-48), where the temperature sensors are utilized to detect the nasal/oral airflow and to detect the temperatures of the body in order to monitor the physiological data of the patient to optimize settings. (Column 7, Lines 64-67). Regarding the location of the sensor on the mask, Miles teaches sensors may be mounted on the mask. (Column 4, Lines 44-45). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Burton/Sullivan/John to include the body movement sensors on the mask as taught by Miles for the purpose of optimizing and monitoring the physiological data of the patient.

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5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burton (WO 97/16216) in view of Sullivan (5,243,971) and John et al. (6,385,486), as applied to claim 4 above, and further in view of Brown (6,032,065).

As to Claim 5, the system of Burton/Sullivan/John discloses a mask assembly, yet does not expressly disclose the particular structure of the EEG electrodes to be made of conductive carbonized rubber material. However, at the time the invention was made the use of conductive carbonized rubber material in EEG electrodes was known. Specifically, Brown discloses the electrodes are made from a pad comprising a conductive carbonized rubber material, for the purpose of providing a low profile electrode. (Column 3, Lines 9-29). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Burton/Sullivan/John to include the use of conductive carbonized rubber material on the EEG electrodes as taught by Brown for the purpose of optimizing the size and shape of the EEG electrode over the prior art.

6. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton (WO 97/16216) in view of Sullivan (5,243,971) and John et al. (6,385,486) as applied to claim 18 above, and further in view of Cui et al. (5,584,296).

As to Claims 21 and 22, the combination of the prior art references teaches a mask assembly with a plurality of sensors, yet does not expressly disclose the use of light sources and high pass filters. However, at the time the invention was made the use of light sources and high pass filters was known. Specifically, Cui teaches

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attaching a light source (36) and a light sensor (32) on a mask so that the light source and light sensor are positioned to contact a person's forehead (Fig 1), illuminating the light source (Column 2, Lines 63-66); detecting the light from the light source (via 32 and 34) as it deflects from the person's skull; and converting (via 20) the detected light into an analog signal. Regarding the filtering technique, the technique utilized would be within the conventional methods of filtering sound since it has been held to be within the general skill of a worker in the art to select a known filtering technique on the basis of its suitability for the intended use as a matter of obvious design choice. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensors of Miles to include a light source and sensors as taught by Cui for the purpose of reading and detecting sensor information.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burton (WO 97/16216) in view of Sullivan (5,243,971) and John et al. (6,385,486) as applied to claim 14 above, and further in view of Tripp, Jr. (H1039).

As to Claim 30, the combination of the prior art references teaches a mask assembly with a plurality of sensors, yet does not expressly disclose a mask seal leakage detector. However, Tripp teaches a perimeter of the mask is adapted to sense leaks (Column 11, Lines 46-53). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensors of Miles to include a leakage detector as taught by Tripp to detect the passage of air between the mask assembly and the external environment.

Response to Arguments

7. Applicant's arguments with respect to claims 1, 2, 4-11, 14-26, 29, and 30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Weismann et al. (6,199,550) discloses a gas delivery device having an EEG sensor, and Torch (6,542,081) discloses an EEG sensor on a mask.

8. The following references are not prior art, but are made of record and considered pertinent to applicant's disclosure. Mumford et al. (2005/0268916 and 2007/0208269), Genger et al. (7,054,680), Schneider et al. (2008/0092898), Rubin et al. (2008/0127978) and Thomas et al. (2004/0144383) discloses additional EEG sensors on gas delivery devices.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 3771

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